

Corrigendum No-04

Amendments of NIT 47- Schedule No.1 (Anesthesia)

Sr	Name of Item	Schedule No	Item No	Final Amendment
1	Anaesthesia Workstation	1	12	h) System should be US FDA approved and confirms to EN 60601-2-13 (Requirement for safety and essential performance of anaesthesia system)
2	Defibrillator	1	25	The unit should be U.S FDA approved
3	Multi Channel Monitor with Central station (Set of 12 Monitors with 1 Central Station)	1	20	The unit should be U.S FDA approved
4	Bedside Monitor for ICU	1	21	The unit should be U.S FDA approved
5	Portable Echo Cardiography Machine (ICU Dedicated Ultrasound and Echo Machine)	1	29	The unit should be U.S FDA approved
6	Isoflurane Vaporiser	1	32	The unit should be U.S FDA approved
7	Sevoflurane Vaporiser	1	33	The unit should be U.S FDA approved
8	Desflurane Vaporizer	1	8	The unit should be U.S FDA approved

Amendment for item no.9 of Schedule no.3 (ENT) of NIT 47

The Specification of NIT 47 Schedule 3 item no. 9 of ENT Dept. “Heavy duty shadow less operating light for ENT OT similar make major + minor (O.T.)” should be read as follows :-

Heavy duty shadow less operating light for ENT OT

- (a) The double dome operating light must be designed for the use in high demanding surgical procedures. State-of-the-art LED bulbs should be used to ensure a low energy consumption and a long service life.
- (b) **The LED OT Light unit should be US FDA approved.**
- (c) Outer handles at the light head should be provided to allow for non-sterile positioning.
- (d) Light head must be designed with smooth transitions and surfaces, without slots, gaps or exposed screwing to ensure fast and effective cleaning.
- (e) The light head with streamlined shape is favourable within laminar flow. The light head must be resistant to disinfectant.
- (f) For sterile positioning an ergonomic, exchangeable and centrally positioned sterile handle within the light head should be provided.
- (g) All main joints of surgical light must be provided with unlimited rotation (360°). Light head and suspension must be sealed dustproof.
- (h) **Classification**
 - a. Protection class acc. to IEC 60601-1 -
 - i. Mains connection component - Protection class 1
 - ii. Light head – SELV
 - b. Protection class acc. to IEC 60529
 - i. Arm system/mains connection component - IP 30
 - ii. Light head - IP 42
 - c. Classification in accordance with EU Directive 93/42/EEC Annex IX - Class I
 - d. UMDNS-Code (Universal Medical Device Nomenclature System) - 12-282
 - e. IEC 60601-1 - Medical electrical equipment – Section 1-1
 - f. IEC 60601-2-41 - Medical electrical equipment – Section 2-41
 - g. IEC 60601-1-2 - Medical electrical equipment – Section 1-2
 - h. Should have US FDA approved, certificate must to be provided.
- (i) The surgical light should be complete with all components for ceiling mount and electrical feed-in, incl. finalised installation.
- (j) Technical data for main dome: - 1nos.
 - i. **Central illumination intensity E_c** **160.000 lux**
 - ii. Light field diameter at a distance of 1 m 200 mm
 - iii. Depth of illumination L1+L2 1300 mm
 - iv. Average Color rendering index Ra 95
 - v. Color rendering index R9 (red) 93
 - vi. Color temperature 5000K

vii. Central illumination at 1m distance with:	
I. Tube	100%
II. one mask:	40%
III. tube and one mask:	40%
IV. two masks:	48%
V. tube and two masks:	48%
viii. Central irradiance Ee	580 W/ m ² ± 50 W/ m ²
ix. Ee/Ec ratio -	3.5 W/m ² x Lux
x. Adjusting the illumination intensity	40000 to 160000 Lux
xi. Number of LED	66 units
xii. Number of LED stripes	11 units
xiii. Service life LED bulbs	approx. 30000 hours
xiv. Replacement of LED bulbs	possible
xv. Ambient light mode (Endolight)	300 Lux
xvi. Diameter of light head	620 mm

(k) Technical data for satellite dome - 1 nos.

i. <u>Central illumination intensity Ec</u>	160.000 lux
ii. Light field diameter	200mm
iii. Depth of illumination L1+L2	1300 mm
iv. Average Color rendering index Ra	95
v. Color rendering index R9 (red)	93
vi. Color temperature	5000K
vii. Central illumination at 1m distance with:	
I. Tube	100%
II. one mask:	41%
III. tube and one mask:	41%
IV. two masks:	49%
V. tube and two masks:	49%
viii. Central irradiance Ee	430 W/m ² ± 50 W/m ²
ix. Ee/Ec ratio	3.5 W/m ² x Lux
x. Adjusting the illumination intensity	40000 to 120000 Lux
xi. Number of LED	48 units
xii. Number of LED stripes	8 units
xiii. Replacement of LED bulbs	possible
xiv. Service life LED bulbs	approx. 30000 hours
xv. Ambient light mode (Endolight)	300 Lux
xvi. Diameter of light head	620 mm